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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,477	08/22/2006	Torsten Branderburger	05116835	1954
26565	7590	06/18/2009		
MAYER BROWN LLP P.O. BOX 2828 CHICAGO, IL 60690			EXAMINER MARCETICH, ADAM M	
			ART UNIT 3761	PAPER NUMBER
			NOTIFICATION DATE 06/18/2009	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ipdocket@mayerbrown.com

Office Action Summary	Application No. 10/550,477	Applicant(s) BRANDERBURGER ET AL.	
	Examiner Adam Marcetich	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. Germany 103 13 760.2, filed on 27 March 2003 has been received.

Claim Rejections - 35 USC § 102 / 103

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-3,5 and 10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Fowles; Thomas A. et al. (US 4632267).

6. Regarding claim 1, Fowles discloses a connector for packings containing parenteral and peritoneal dialysis liquids (col. 1, lines 4-17, col. 2, lines 50-58, Figs. 1-3, port system); comprising:

a connecting part with a passage (col. 2, lines 50-58, Fig. 1, port 12 having lumen);

which can accommodate a rod or a spike for filling or withdrawal of liquid (col. 2, lines 66-3, Fig. 1, opening 22 for needle or other access means);

a closure part which can be fitted onto the connecting part and closes the passage in the connecting part (col. 2, lines 50-58, Fig. 1, closure 10);

characterized in that the connecting part has an elastically deformable pinching-off part (see annotated Fig. 1 of Fowles below),

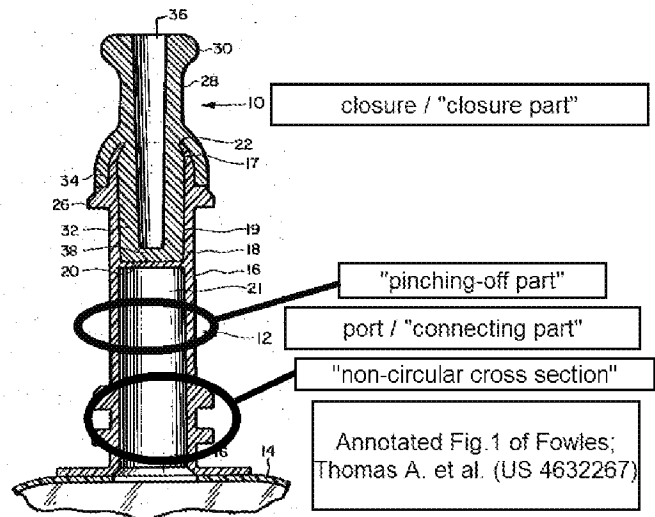
which re-assumes its original shape again after pinching with a pinching device (col. 4, lines 32-37, especially lines 37-39, port 12/112 formed of polyethylene, a deformable polymer); and

is designed as a tubular portion with a noncircular cross section, and

in that the pinching-off part merges into a base part which widens to both sides and which can be integrated in the packing (Fig. 1, lower end of port 12 widened to both sides and integrated into container 14).

When the structure or composition recited in the reference is substantially identical to that of the claims of the instant invention, claimed properties or functions presumed to be inherent (MPEP 2112-2112.01). A prima facie case of either anticipation or obviousness has been established when the reference discloses all the limitations of a claim (in this case, a polyethylene connecting part comprising a pinching-off part) except for a property or function (in the present case, the ability to re-assume its original shape after pinching) and the examiner can not determine whether or not the reference inherently possesses properties that anticipate or render obvious the claimed invention but has a basis for shifting the burden of proof to applicant, as per *In re Fitzgerald*, 619 F.2d 67, 205 USPQ 594 (CCPA 1980).

regarding the limitation of a “pinching device,” Examiner interprets the language “after pinching with a pinching device” as functional language, not specifically claiming the structure of a pinching device. That is, claim 1 specifies a function of a pinching-off part but does not specifically claim the structure of a pinching device.



7. Regarding claims 2, 3, 5 and 10, Fowles discloses:

[2] a closure part and the connecting part secured with a snap fit (col. 3, lines 14-24, Fig. 1, closure 10 and port 12 fit together with tapered end 17);

[3] a self- sealing membrane arranged between the connecting part and the closure part that can be pierced by the spike for withdrawal of the liquid (col. 2, lines 59-66, Fig. 1, partition wall 20 dividing tubular bore 18 into upper bore 19 and lower bore 21; Examiner interprets the wall 20 as substantially “between” a connecting part and closure part, since it is narrower than the lumens of both closure 10 and port 12. additionally, wall 20 is between closure 10 and the lower bore 21 of port 12);

[5] a closure part having a cap-shaped bottom part which is adjoined via an annular break zone (col. 3, lines 49-58, Fig. 2, scored line 150);

[5] by a top part that can be broken off (Fig. 3, detached portion of closure 110);
and

[10] a packing for medical liquids, particularly an infusion, transfusion or enteral bag, having at least one connector as claimed in claim 1 (col. 1, lines 4-17, col. 2, lines 50-58, Fig. 1, container 10 for parenteral or peritoneal dialysis liquids).

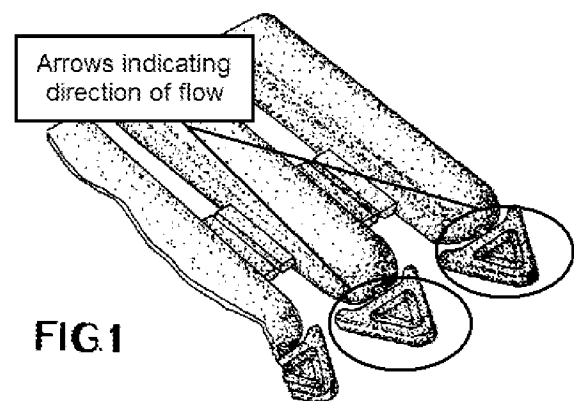
8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fowles; Thomas A. et al. (US 4632267) as applied to claims 2, 3, 5 and 10 above, in view of Burns (US 5,494,170).

9. Regarding claim 4, Fowles discloses the invention as substantially claimed, see above. However, Fowles lacks clamping with elastic deformation between a connecting part and a closure part as claimed [claim 4]. Burns discloses a closure part and connecting part secured with a snap fit (column 2, lines 61-67 and column 3, lines 13-23, Fig. 1, cam ring 4 and cooperating cam follower ring 16 forming snap-fit), further

comprising a self-sealing membrane held clamped with elastic deformation between a connecting part and a closure part (column 2, lines 53-58 and Fig. 1, stopper 12 depicted as held between tube 1 and shield 11). Burns provides the advantage of simple construction in addition to multiple withdrawals. Additionally, holding a membrane with elastic deformation allows a different material to be used for a sealing membrane which may be more adaptable for repeated piercing. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fowles as discussed with the clamped, self-sealing membrane as taught by Burns in order to provide simple construction and multiple withdrawals.

10. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowles; Thomas A. et al. (US 4632267) as applied to claims 2, 3, 5 and 10 above, in view of Knierbein (US 6,364,143).

11. Regarding claim 6, Fowles discloses the invention substantially as claimed, see above. However, Fowles lacks a flat grip piece as claimed [claim 6]. Knierbein discloses Knierbein discloses a connector for packings containing enteral solution



Annotated Fig. 1 of LeMarr et al. (US D456,507)
(col. 1, lines 4-13, col. 3, lines 32-41, Fig. 1, connector 1), further comprising a

connector characterized in that the top part that can be broken off is designed as a flat grip piece (Fig. 1, wings 13 and 14 forming a flat grip piece).

Knierbein increases the leverage applied when detaching a frangible element. That is, a flat piece presents greater torque. One would be motivated to modify Fowles with the flat grip piece as taught by Knierbein to increase torque since Fowles calls for a grip that detaches a closure member (col. 3, lines 8-17).. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fowles as discussed with the flat grip piece as taught by Knierbein in order to increase torque when opening a closure part.

12. Regarding claim 9, Fowles discloses the invention substantially as claimed, see above. However, Fowles lacks a boat shape as claimed [claim 9]. Knierbein discloses a connector characterized in that the base part is designed in the shape of a boat (col. 3, lines 32-40 and Fig. 1, boat-shaped lower part 3 having boat-shape). Knierbein provides the advantage of effectively draining a liquid container. For example, a boat shape drains contents of a bag effectively when inverted. One would be motivated to modify Fowles with the boat shape as taught by Knierbein to drain a liquid container effectively.

13. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowles; Thomas A. et al. (US 4632267) in view of Knierbein (US 6,364,143) as applied to claims 6 and 9 above, further in view of LeMarr et al. (US D456,507).

14. Regarding claims 7 and 8, Fowles in view of Knierbein discloses the invention as substantially claimed, see above. However, Fowles in view of Knierbein lacks an arrow

designed as a recess and/or as a raised structure as claimed [claims 7 and 8]. LeMarr discloses a nebulizer vial comprising an arrow designed as a recess and/or as a raised structure (see annotated Fig. 1 below). LeMarr provides the advantage of showing a user where fluid will exit a container when opened. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Fowles in view of Knierbein as discussed with the arrow as taught by LeMarr in order to instruct a user.

Response to Arguments

15. Applicant's arguments, see telephone interview on 09 March 2009 and p. 4-8 filed 24 March 2009 with respect to the rejection(s) of claim(s) 1-10 under 35 USC § 102 and 103 over Knierbein Burns and LeMarr have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made under 35 USC § 102 and 103 over Fowles, Knierbein Burns and LeMarr.

16. Applicant contends that Knierbein lacks a resealable membrane and connecting part which can accommodate a rod or spike for filing, since spike 17 ruptures barrier module 15 but does not reseal. Examiner cites Fowles as teaching a resealable membrane in the new grounds of rejection.

17. Applicant submits that Knierbein lacks a non-circular cross-section, since it connects to a non-deformable connector with a circular cross-section and therefore has a circular cross section. Examiner cites Fowles as teaching a non-circular cross-section and notes that Applicant has not claimed a non-circular axial cross-section. That is, Examiner interprets the cross-section in Figs. 1-3 of Fowles as a non-circular cross-section. Additionally, Examiner cites Watt; William E. R. (US 4150673) as relevant to Applicant's disclosure, as teaching non-circular axial cross-sections. No rejection is made over Watt in this Office Action.

18. Applicant reasons that if the tubular upper part of Knierbein is elastically deformable, then it would not seal as claimed. Examiner notes that Fowles does not practice threading as Knierbein. Therefore, port 12/112 of Fowles, which is formed of polyethylene, is capable of elastic deformation and re-assuming its shape after pinching.

19. Applicant asserts that Burns and LeMarr fail to remedy the deficiencies of Knierbein, namely a connecting part which can accommodate a rod or spike for filing and a non-circular, elastically deformable connecting part. Examiner instead cites Fowles as teaching these limitations in the new grounds of rejection. Examiner cites Burns as teaching a membrane held with compression, and cites LeMarr as teaching an arrow designed as a recess and/or as a raised structure.

Conclusion

20. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

- ◆ Van Der Heiden; Johannes et al. US 5368586
- ◆ Watt; W. E. R. US 3986507
- ◆ Grimes; Robert G. US 4415393
- ◆ Difiglio; Joseph John US 3994412
- ◆ Schmidt; Josef et al. US 4892222
- ◆ Ducay; James et al. US 4903855
- ◆ Fowles; Thomas A. US 4836397
- ◆ Rosemeier; Friedrich et al. US 4295495
- ◆ Watt; William E. R. US 4150673

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

22. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

23. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

24. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

25. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
16 June 2009